BLUTSPENDE SRK
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Summary of the Risk Management Plan (RMP) for Serum autologous blood donation Zurich, eye drops

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Active substance	*Serum humanum autologum*

DISCLAIMER

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimize them.

The RMP summary of Serum autologous blood donation Zurich, eye drops is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of Serum autologous blood donation Zurich, eye drops is the "Arzneimittelinformation/Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic.

Stiftung Zürcher Blutspendedienst SRK, Zürich, Switzerland is fully responsible for the accuracy and correctness of the content of this published summary RMP Serum autologous blood donation Zurich, eye drops.

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Summary of risk management plan for Serum autologous blood donation Zurich, eye drops

This is a summary of the risk management plan (RMP) for serum autologous blood donation Zurich, eye drops. The RMP details important risks of serum autologous blood donation Zurich, eye drops, how these risks can be minimised, and how more information will be obtained about serum autologous blood donation Zurich, eye drops risks and uncertainties (missing information).

Serum autologous blood donation Zurich, eye drops summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how serum autologous blood donation Zurich, eye drops should be used.

This summary of the RMP for serum autologous blood donation Zurich, eye drops should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of serum autologous blood donation Zurich, eye drops RMP.

I. The medicine and what it is used for

Serum autologous blood donation Zurich, eye drops is authorised for the treatment of dry eye (*keratoconjunctivitis sicca*) in patients aged 18 years and older who do not experience symptom relief with other approved therapies (see Professional Information for the full indication). It contains *serum humanum autologum* as the active substance and it is given by topical eye administration.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of serum autologous blood donation Zurich, eye drops, together with measures to minimise such risks and the proposed studies for learning more about Serum autologous blood donation Zurich, eye drops risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicines packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

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II.A List of important risks and missing information

Important risks of serum autologous blood donation Zurich, eye drops are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of serum autologous blood donation Zurich, eye drops. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

List of important risks and missing information *(from Part II: Module SVIII)*	
Important identified risks	- Transmission of infectious disease related to the procedure - Contamination during use by the patient
Important potential risks	- Iron deficiency (Anaemia) related to the procedure - Rare therapy-related complications
Missing information	- Pregnant or breastfeeding women - Paediatric population - Patients using contact lenses - Long-term efficacy

II.B Summary of important risks

Important identified risks	
Risk factors and risk groups	*- Transmission of infectious disease related to the procedure* *- Contamination during use by the patient*
Risk minimisation measures	Listed under "Professional Information" and "Information for the patient".
Additional pharmacovigilance activities	Observational study, ASED-patients

Important potential risks	
Risk factors and risk groups	*- Iron deficiency (Aneaemia) related to the procedure* *- Rare therapy-related complications*
Risk minimisation measures	Listed under 'Professional Information` and Information for the patient.
Additional pharmacovigilance activities	Observational study, ASED-patients

Missing information	
Risk factors and risk groups	- Pregnant or breastfeeding women - Paediatric population - Patients using contact lenses - Long-term efficacy
Risk minimisation measures	Listed under ‘Professional Information` and Information for the patient.
Additional pharmacovigilance activities	Observational study, ASED-patients

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

The following studies are conditions of the marketing authorisation:

Study short name: Observational study, ASED-patients

Purpose of the study: *To ensure adequate monitoring of the safety and efficacy of ASED in the treatment of adults with dry eye disease.*

II.C.2 Other studies in post-authorisation development plan

There are no further studies required for serum autologous blood donation Zurich, eye drops.